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10/663,562	09/16/2003	Nina Rautonen	17031	2985

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EXAMINER	
BLAND, LAYLA D	

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1623	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/663,562	RAUTONEN ET AL.	
	Examiner	Art Unit	
	LAYLA BLAND	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 April 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,5-14,16-20,24,26-28,30 and 32-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,5-14,16-20,24,26-28,30 and 32-34* _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on - is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/10/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This office action is a response to Applicant's amendment submitted April 21, 2008, wherein claims 1, 9-12, 24, 32, and 33 are amended and claims 21-23 and 31 are canceled.

In view of the cancellation of claims 21-23 and 31, all rejections made with respect to those claims in the previous office action are withdrawn.

In view of Applicant's amendment submitted April 21, 2008, the rejection of claims 9-12 under 35 USC 112, first paragraph, for lacking enablement for the treatment of disease using polydextrose, is withdrawn.

In view of Applicant's remarks submitted April 21, 2008, the rejection of claims 5-14, 16-22, 24-28, 30, and 32-34 under 35 U.S.C. 112, second paragraph, for being indefinite regarding which condition is to be treated, is withdrawn.

In view of Applicant's amendment submitted April 21, 2008, the rejection of claims 1, 5-13, 19, 27, and 28 under 35 USC 102(b) as being anticipated by Jie et al. is withdrawn. As amended, the claims require administration of polydextrose in a food product which is yogurt, baby's milk formula, sour milk, curdled milk, dry milk, or crout. Jie et al. teach administration of polydextrose in water and thus the claims are not anticipated.

In view of Applicant's amendment submitted April 21, 2008, the rejection of claims 5-14, 16-19, 21, 22, 26-28, and 30-34 under 35 USC 102(b) as being anticipated by Olinger et al. is withdrawn. As amended, the claims require administration of polydextrose in a food product which is yogurt, baby's milk formula, sour milk, curdled

milk, dry milk, or crout. Olinger et al. teach administration of polydextrose in a chocolate bar and thus the claims are not anticipated.

The following modified rejection was necessitated by Applicant's amendment submitted April 21, 2008, wherein independent claim 1 was amended to require polydextrose administered in yogurt, baby's milk formula, sour milk, curdled milk, dry milk or crout.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 5-13, 19, 20, 24, 27, and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jie et al. (Am J Clin Nutr 2000, 72:1503-9, of record).

Jie et al. teach a study in which 4-12 grams of polydextrose per day were consumed by volunteers in order to study the physiologic effects. The polydextrose used was Litesse, provided by Danisco Cultor [page 1504, first paragraph], which is purified. Fecal pH decreased proportionally to polydextrose intake. Short-chain fatty acid production (butyrate) increased with polydextrose ingestion. *Bacteroides* (infection-causing bacteria) species decreased and *Lactobacillus* and *Bifidobacterium* (lactic acid bacteria) species increased. [page 1503, Results] Jie et al. also teach that polydextrose is partially fermented in the large intestine and fermentation of

polydextrose leads to diminished putrefactive microflora and suppressed production of carcinogenic metabolites [page 1503, column 2, lines 13-19]. A high fecal output and low bowel pH can suppress the production of enteric toxins, which plays an important role in the prevention of diverticulosis and reduces the risk of bowel cancer [page 1506, column 2, lines 16-18].

Jie et al. do not teach the administration of polydextrose in a food product.

It would have been obvious to one of ordinary skill in the art to administer polydextrose in a food product to a subject; particularly a subject having conditions associated with digestive and bowel health. Jie et al. teach that consumption of polydextrose improved bowel function, softened the feces, improved the ease of defecation, promoted the proliferation of favorable intestinal microflora and decrased the pH of the bowel [page 1508, last paragraph]. The skilled artisan could easily conceive of administering a compound that is useful for digestive and bowel health into a food composition. Furthermore, it is obvious to administer a composition that is useful for digestive and bowel health to subjects having conditions associated with digestive and bowel health, such as celiac disease and food allergy, or other conditions which affect digestive and bowel health.

Response to Arguments

Applicant's arguments filed April 21, 2008 have been fully considered but they are not persuasive.

Applicant argues that the claims are limited to specific food products, which are all dairy products, that the study carried out by Jie et al. was on Chinese people, and

that the Chinese diet does not include dairy products. It is unclear how crout (sauerkraut, page 18 of the specification) is considered a dairy product. The examiner's understanding is that sauerkraut is pickled cabbage. Clarification is requested. Although Jie's study was conducted on Chinese subjects, the skilled artisan would not expect the properties and benefits of polydextrose to be limited to Chinese people or to non-dairy diets.

In response to applicant's argument that Jie et al. do not discuss the ability of polydextrose to provide energy to intestinal microflora in a controlled and sustained manner, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). It would be obvious to administer polydextrose in any food product in order to obtain the benefits of dietary fiber, as discussed above.

Thus, the rejection is maintained.

The following rejections were necessitated by Applicant's amendment submitted April 21, 2008, wherein independent claim 1 was amended to require polydextrose administered in yogurt, baby's milk formula, sour milk, curdled milk, dry milk or crout. As a result of this amendment, claims 14, 16-19, 30, and 32-34, previously rejected as anticipated by Olinger et al., are no longer anticipated. Claims 14, 16-19, 30, and 32-34

now contain limitations regarding polyols and limitations regarding types of food products, where previously these limitations were in separate claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 5-14, 16-19, 27, 28, 30, and 32-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Takemori et al. (US 5,711,982, January 27, 1998).

Takemori et al. teach a de-lactose milk powder containing polydextrose [column 9, Example 4]. The de-lactose milk powder was used to prepare chocolate, which contained 20.5 parts polydextrose and 14 parts lactitol [column 9, lines 39-47]. The chocolate was administered to a panel of high school students [column 10, lines 26-45]. Thus, the high school students were administered dry milk containing polydextrose, along with lactitol, in a ratio of about 1.5:1.

The instant specification, page 9, states that "imbalanced" fermentation means that energy available for bacteria in the colon is not distributed evenly, which could lead to high amounts of lactic acid. The specification further states that if microorganisms in

the colon use proteins as an energy source, imbalanced fermentation could result. Further, if too much energy is released in the proximal part of the colon, a boost of fermentation is obtained which gives rise to imbalance at a later stage in the colon. High school students (and any other humans) are likely to consume protein and foods which are rapidly digested and thus are considered "subject to a risk of lactic acid accumulation due to imbalanced colon fermentation."

Takemori is silent regarding the purification of polydextrose, but it is considered very likely that the polydextrose was purified because it was administered to children.

Takemori is silent regarding synergism between polydextrose and lactitol, but the amounts taught by Takemori fall within the preferred ranges given on page 16 of the instant specification.

Thus, Takemori et al. teach administration of the same composition to the same patient population and the claims are anticipated.

Claims 1, 5-14, 16, 17, 19, 24, 26-28, 30, and 32-34 are rejected under 35 U.S.C. 102(e) as being anticipated by Shaw Craig et al. (US 2003/0008843, January 9, 2003)

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Shaw Craig et al. teach a method for suppressing the appetite of a mammal, comprising administering xylitol and polydextrose in a ratio of about 1:5 to 5:1 [claim 9]. Yogurt containing xylitol and polydextrose in a 1:1 ratio was administered to human subjects [0077]. Polydextrose or hydrogenated polydextrose which is at least 90% pure is desired [0036-0038].

As discussed above, any humans are considered "subject to a risk of lactic acid accumulation due to imbalanced colon fermentation." Thus, Shaw Craig et al. teach administration of the same composition to the same patient population and the claims are anticipated.

The following new rejections are based upon a new reference submitted with Applicant's information disclosure statement on January 10, 2008.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 5-13, 19, 27, and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Solomons et al. (J. Lab. Clin. Med, May 1985, pages 585-592, PTO-1449 submitted January 10, 2008).

Solomons et al. teach a study in which healthy adults of ages 19-45 years were administered 360 ml of intact milk or hydrolyzed milk containing 18 grams of

polydextrose [page 586, Methods]. Intact milk is no more than dry milk with water, so the claims are anticipated. Furthermore, hydrolyzed milk is often used as infant formula; thus it can be considered a baby's milk formula. It is noted that no definition of "aged mammal" has been provided. A 45 year old human is in the second half of his or her lifespan, considering an average human lifespan of about 75-80 years, so he or she could reasonably be considered aged and claim 20 is anticipated. Solomons et al. are silent regarding whether the polydextrose was purified; however, the polydextrose was administered to humans so it was likely purified. As discussed above, any humans are considered "subject to a risk of lactic acid accumulation due to imbalanced colon fermentation."

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Solomons et al. (J. Lab. Clin. Med, May 1985, pages 585-592, PTO-1449 submitted January 10, 2008) in view of Borden et al. (US 5,601,863, February 11, 1997).

Solomons teaches as set forth above.

Solomons does not teach the use of hydrogenated polydextrose.

Borden et al. teach that polydextrose and hydrogenated polydextrose are both enzyme-resistant and functional equivalents as food additives [columns 1-2 and paragraph bridging columns 6-7].

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use hydrogenated polydextrose in the method of Solomons et al. Hydrogenated polydextrose is known as a functional equivalent of polydextrose, having improved properties such as color and flavor.

Conclusion

Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on January 10, 2008 and Applicant's amendment submitted April 21, 2008 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609.04(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAYLA BLAND whose telephone number is (571)272-9572. The examiner can normally be reached on Tuesday - Friday, 8:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anna Jiang can be reached on (571) 272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Shaojia Anna Jiang, Ph.D./
Supervisory Patent Examiner, Art Unit 1623

/Layla Bland/
Examiner, Art Unit 1623